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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,486	03/26/2004	Mitsuru Furusawa	690116.401C1	8553

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EXAMINER	
RIGGINS, PATRICK S	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,486	FURUSAWA, MITSURU	
	Examiner	Art Unit	
	Patrick S. Riggins	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-124* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-94 drawn to a method of regulating an error rate in a cell or organism, and the cell or organism produced by that method, classified in class 435, subclass 6.

II. Claims 95 and 96, drawn to a method of screening to identify and produce a nucleic acid that encodes a gene having a regulated trait and the nucleic acid identified and produced by the method, classified in class 435, subclass 6.

III. Claims 97 and 98, drawn to a method for identifying and producing a polypeptide encoded by a gene having a regulated hereditary trait and the polypeptide identified and produced by this method, classified in class 435, subclass 69.1.

IV. Claims 99 and 100, drawn to a method for identifying and producing a metabolite of an organism having a regulated hereditary trait and a metabolite identified and produced by this method, classified in class 435, subclass 41.

V. Claims 101-110, drawn to a nucleic acid encoding a polymerase, vectors, and cells comprising these nucleic acids, classified in class 536, subclass 23.2.

VI. Claim 111, drawn to an organism comprising a nucleic acid encoding a DNA polymerase, classified for example in class 800, subclass 8

VII. Claim 112, drawn to a product substance produced by a cell comprising a nucleic acid encoding a polymerase, classified for example in class 530, subclass 300.

VIII. Claims 113 and 114, drawn to a nucleic acid in a cell comprising a nucleic acid encoding a DNA polymerase, classified in class 536, subclass 23.1.

IX. Claim 115, drawn to a method of testing a drug using a cell comprising a nucleic acid encoding a DNA polymerase, classified in class 435, subclass 4.

X. Claim 116, drawn to a method of testing a drug using an organism comprising a nucleic acid encoding a DNA polymerase, classified in class 800, subclass 3.

XI. Claims 117-124, drawn to a set of two polymerases for regulating the conversion rate of a hereditary trait of an organism and a use of those polymerases, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I is related to but distinct from each of the Groups II-XI. Invention I is drawn to various methods of regulating the conversion rate of a hereditary trait by regulating the error prone frequency in a cell or organism. The other method groups are distinct from Group I because the methods in Groups II-IV, IX and X are all relate to identification and purification of nucleic acids, polypeptides, metabolites, or drugs. The process of Group I is not intended to identify any component. Thus the process steps and expected end product of Group I are different from those process steps and end products expected for any of the methods of Groups II-IV, IX, and X. Additionally, the products of Groups V-VIII and XI are not produced by or used in the methods of Group I. To search the methods of Group I would not return results pertinent to any of the remaining Groups. Therefore to search Group I with the other Groups would place an undue search and examination burden.

3. Invention II is related to but distinct from each of Groups III-XI. Invention II is drawn to a method for identifying and producing a nucleic acid encoding a gene having a regulated hereditary trait. Groups III and IV are drawn to methods of identifying and producing a polypeptide or metabolite involved in a regulated hereditary trait. The steps to identify and produce a nucleic acid are distinct from the steps to identify and produce a polypeptide or a metabolite. Additionally, the end products are obviously distinct as the Group II methods result in the production of a nucleic acid while the methods of Groups III and IV result in the production of a polypeptide or metabolite. Similarly the methods of Group II use different process steps and have different expected end products form the methods of both Groups IX and X. The products claimed in Groups V-VIII and XI are distinct biochemically, structurally and functionally from any product used or produced by the methods of Group II. As a search of the methods of Group II would not return results pertinent to any of Groups III-XI, a search of Group II with these other groups would place an undue search and examination burden.

4. Invention III is related to but distinct from each of Groups IV-XI. Invention III is drawn to a method for identifying and producing a polypeptide involved with a regulated hereditary trait. Group IV is drawn to a methods of identifying and producing a metabolite involved in a regulated hereditary trait. The steps to identify and produce a polypeptide are distinct from the steps to identify and produce a metabolite. Additionally, the end products are obviously distinct as the Group III methods result in the production of a polypeptide while the method of Group IV result in the production of a metabolite. Similarly the method of Group III uses different process steps and has different expected end product from the methods of both Groups IX and X. The products claimed in Groups V-VIII and XI are distinct biochemically, structurally and

functionally from any product used or produced by the methods of Group III. As a search of the methods of Group III would not return results pertinent to any of Groups IV-XI, a search of Group III with these other groups would place an undue search and examination burden.

5. Invention IV is related to but distinct from each of Groups V-XI. Invention IV is drawn to a method for identifying and producing a metabolite involved with a regulated hereditary trait. Groups IX and X are both drawn to methods of testing a drug the methods of which would use different process steps and have different expected results from the methods of Group IV. Additionally, the end products are obviously distinct as the Group IV method results in the production of a polypeptide while the methods of Groups IX and XI result in the identification of a drug. The products claimed in Groups V-VIII and XI are distinct biochemically, structurally and functionally from any product used or produced by the methods of Group IV. As a search of the methods of Group IV would not return results pertinent to any of Groups V-XI, a search of Group IV with these other groups would place an undue search and examination burden.

6. Invention V is related to but distinct from each of Groups VI-XI. Invention V is drawn to nucleic acids encoding a DNA polymerase, vectors and cells comprising these nucleic acids. These are distinct structurally, biochemically, and functionally from any of the products in Groups VI-VIII and XI. The products of Group V are neither produced by nor useful in the methods of Groups X. As a search of the nucleic acids, vectors, and cells of Group V would not return results pertinent to any of Groups VI-VIII, X and XI, a search of Group V with these other groups would place an undue search and examination burden.

7. Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products of Group V can be used in a variety of other methods including to screen for the presence of expressed polymerases in a cell. To search the nucleic acids of Group V would not necessarily return results pertinent to the method of Group IX. Thus to examine these together would place an undue search and examination burden.

8. Invention VI is related to but distinct from each of Groups VII-XI. Invention VI is drawn to an organism comprising nucleic acids encoding DNA polymerases. These organisms are distinct structurally, biochemically, and functionally from any of the products in Groups VII, VIII, and XI. The organisms of Group VI are neither produced by nor useful in the methods of Groups IX. As a search of the organisms of Group VI would not return results pertinent to any of Groups VI-VIII, IX, and XI, a search of Group VI with these other groups would place an undue search and examination burden

9. Inventions VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products of Group VI can be used in a variety of other methods including as appositive control in screens for the presence of expressed polymerases in cells. To search the organisms of Group VI would not necessarily return results pertinent to the method of Group X. Thus to examine these together would place an undue search and examination burden.

10. Invention VII is related to but distinct from each of Groups VII-XI. Invention VII is drawn to an undefined product substance. As there is no apparent structure disclosed regarding these products, there is no way to even ascertain whether they share any real relationship to any of the other Groups. They are distinct structurally, biochemically, and functionally from any of the products in Groups VIII and XI. The products of Group VII are neither produced by nor useful in the methods of Groups IX or X. As a search for product substances of Group VII would not return results pertinent to any of Groups VIII, X, or XI, a search of Group VII with these other groups would place an undue search and examination burden.

11. Invention VIII is related to but distinct from each of Groups IX-XI. Invention VIII is drawn to unspecified and undefined nucleic acids related to a regulated hereditary trait. These are distinct structurally, biochemically, and functionally from any of the products in Group XI. The products of Group VIII are neither produced by nor useful in the methods of Groups IX or X. As a search of the unspecified and undefined nucleic acids of Group VIII would not return results pertinent to any of Groups IX-XI, a search of Group VIII with these other groups would place an undue search and examination burden.

12. Invention IX is related to but distinct from each of Groups X and XI. Invention IX is drawn to a method for testing a drug that has an effect on cell that is a model of a disease having a regulated hereditary trait. The process steps used for testing a drug against a cellular disease are distinct from those process steps necessary to test in an organism as in Group X. Additionally, the method of Group IX would not produce or use the products of Group XI. As a search of the methods of Group IX would not return results pertinent to either of Groups X or XI, a search of Group IX with these other groups would place an undue search and examination burden.

13. Invention X is related to but distinct from Group XI. Invention X is drawn to a method for testing a drug that has an effect on cell that is a model of a disease having a regulated hereditary trait. The process steps used for testing a drug in an organismal model for a disease would not use or produce the products of Group XI. As a search of the methods of Group X would not return results pertinent to Group XI, a search of Group X with Group XI would place an undue search and examination burden.

14. This application contains claims directed to the following patentably distinct species:

15. Should any of the above Groups be elected, Applicant must further elect as follows:

a. Applicant must elect a polymerase as defined in claims 13, 14, 58, and 59.

b. Applicant must elect the nature of the claimed method of modifying the error-prone frequency in the cell, i.e. whether the error prone frequency is higher or lower in the cells as in claims 20, 21, 65, and 66.

c. Applicant must elect the variety of cell or organism in which the method is to take place. That is Applicant must elect a Gram-positive cell versus a eukaryotic cell as in claims 28 and 73. And if applicant elects a eukaryotic cell the type of cell must be elected from those presented in claims 31 and 32 and 76 and 77.

d. Applicant must elect whether a unicellular or multicellular organism is used as defined in claims 30 and 75.

e. Applicant must elect an environment as defined in claims 38 and 83.

f. Applicant must elect from a cancer cell, tissue, or organism as defined in claims 39-41 and 84-86.

g. Applicant must elect a condition as defined in claims 44 and 89.

h. In a more general sense Applicant must elect the nature of the modification of the error prone frequency in the cell. Is the method as performed in Example 1, or Example 2?

i. In Group XII Applicant must further elect whether the polymerases encoded are from Gram-positive bacteria or a eukaryotic organism. Applicant must further identify the nature of the mutation of claims 103 and 104. Also within Group XII, Applicant must elect the cell as defined in claims 107-109.

16. The species are independent or distinct because the various polymerases, cell types, organisms, environments, conditions, and indeed the nature of the method performed all have wide ranging differences in the nature that they may be searched and indeed in the different options which must be elected all have different considerations regarding utility, enablement, and description. As such to search and examine each of the species would place an undue search and examination burden.

17. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits for each of the above requirements to which the claims shall be restricted if no generic claim is finally held to be allowable.

18. If Applicant were to elect Group I above, further election must be made with regard to the Groups below.

19. Restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 17 and 62, drawn to a method of regulating the error prone frequency of gene replication in a cell by introducing a DNA polymerase variant in to a cell using homologous recombination, classified in class 435, subclass 463.

B. Claims 17 and 62, drawn to a method of regulating the error prone frequency of gene replication in a cell by introducing a DNA polymerase variant in to a cell using a plasmid, classified in class 435, subclass 455.

20. Subgroups A and B are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the two subgroups define different steps for carrying out the generic processes. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. To search the different steps required to perform the methods as claimed in either of Subgroups A or B would not return results pertinent to the other of Subgroups A or B. This would clearly place an undue search and examination burden on the Office.

21. Within this further election, Applicant must indicate the polymerase to be examined as defined in claims 18, 19, 63, and 64.

22. Claims 1 and 16 link(s) inventions A and B. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 16. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked

inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

23. **Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In addition to the elections required above, if Applicant elects Group I, Applicant must further elect as defined in the requirement below.

Conclusion

24. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.
Examiner
Art Unit 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER